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Plaintiff Comanche County Memorial Hospital*

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

COMANCHE COUNTY MEMORIAL
HOSPITAL, on behalf of itself and all others
similarly situated,

Plaintiff,

v.

GENENTECH, INC., ROCHE HOLDING AG,
ROCHE HOLDING LTD., and ROCHE
HOLDINGS, INC.

Defendants.

CASE NO.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff, Comanche County Memorial Hospital (“Plaintiff”), brings this class action on behalf of itself and all others similarly situated (“Class Members”) against Defendants Genentech, Inc. (“Genentech”), Roche Holding AG, Roche Holding Ltd., and Roche Holdings, Inc. (collectively referred to as “Roche Defendants”).

NATURE OF THE ACTION

1
2 1. This is a proposed class action alleging that Defendant Genentech has engaged in
3 a course of conduct with regard to its anticancer drug Herceptin (“Herceptin” or “the Product”),
4 which is unlawful, unfair, and fraudulent in order to increase sales to healthcare providers.

5 2. Defendant, Genentech is a biotechnology company and a wholly owned affiliate
6 and subsidiary of Roche Defendants.

7 3. Roche Defendants comprise one of the world’s largest pharmaceutical companies,
8 manufacturing and marketing both pharmaceutical and diagnostic products throughout the world.
9 Roche has many pharmaceutical and diagnostic sites around the world – including several
10 locations in the United States.

11 4. Genentech manufactures and markets the cancer drug Herceptin in multi-dose
12 vials. It warrants and represents the amount of Herceptin sold in each vial, and provides specific
13 instructions regarding the calculation of the dosage and the amount of Herceptin to be
14 administered to each patient.

15 5. At all relevant times, Genentech misrepresented the amount and/or the
16 concentration of Herceptin in each sold vial, forcing Plaintiff, a healthcare facility treating, *inter*
17 *alia*, cancer patients, to purchase extra, unnecessary Herceptin vials.

18 6. Plaintiff relied on Genentech’s misrepresentations, incurring expenses for the
19 extra, unnecessary vials of Herceptin it was forced to purchase. Plaintiff’s reliance on
20 Genentech’s misrepresentations was well known to Defendants.

JURISDICTION AND VENUE

21
22 7. This Court has personal jurisdiction over the parties in this case. Defendant
23 Genentech is a Delaware corporation with headquarters in this District. Defendant Roche is a
24 foreign corporation with its U.S. headquarters in this District.

25 8. This Court has subject matter jurisdiction over this action pursuant to the Class
26 Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because at least one Class Member is of
27 diverse citizenship from Defendants, there are more than 100 Class Members nationwide, and
28 the aggregate amount in controversy exceeds \$5,000,000.

15. Defendant Genentech and Roche Defendants will be collectively referred to as “Defendants.”

FACTUAL BACKGROUND

A. Product History and Use

16. Herceptin was approved in 1998 by the Food and Drug Administration (FDA) for the treatment of metastatic breast cancer. Herceptin is the Genentech trade name for trastuzumab, a monoclonal antibody that binds to and inactivates the Human Epidermal Growth Factor Receptor-2 (HER2) on the walls of the cancer cells, thus preventing the proliferation of those cells. HER2 receptors are over-expressed in certain cancers, mainly a subset of breast cancers and some gastric cancers (HER-2 positive cancers). The increased number of HER2 receptors in those cancers leads to faster growth and metastasis of the cancer. By binding and inactivating the HER2 receptors, Herceptin slows the growth of the cancer and leads to longer survival rates in late-stage (metastatic) HER2-positive cancer patients.

17. Herceptin was initially approved strictly for treatment of metastatic breast cancer, but its use as adjuvant therapy (treatment in conjunction with other cancer drugs) has since expanded to treat early stage HER-2 positive breast cancers and as a treatment after surgery for reducing the risk of recurrence of the disease. Herceptin is also approved for the treatment of HER2-positive metastatic cancer of the stomach or gastroesophageal junction, in combination with chemotherapy.

18. Herceptin is the only approved effective anticancer therapy on the market for the treatment of HER2-positive tumors and is therefore the dominant breast cancer drug on the market.

19. Herceptin is extremely expensive. It costs about \$70,000 for a course of treatment, which normally consists of a full year of weekly infusions (52 treatments). Since its purchase of Genentech, Roche has been steadily building the sales of this drug around the world. The world-wide Herceptin sale was estimated to be near \$5 billion in 2011, and over \$6 billion in 2012.

20. In 2014, Genentech announced that it no longer distributed Herceptin through the general line wholesalers. Instead it has since marketed Herceptin, along with two other blockbuster cancer drugs, through its specialty distributors. This practice has deprived hospitals and oncology clinics from standard industry discounts routinely offered by general wholesalers, with Genentech and its distributors further profiting from the price difference.¹

B. Preparation and Administration of Herceptin

21. Herceptin is marketed in multi-dose vials, with each vial labeled and warranted by Genentech as containing 440 milligrams (mg) of the drug.²

22. Herceptin is a biological molecule and can therefore easily break down and lose its potency, especially when dissolved as a solution. For this reason, it is marketed as a “lyophilized” powder³ which is to be dissolved in a liquid (“diluent,” normally sterile water containing benzyl alcohol) also provided by Genentech, prior to administration of the drug. The mixing process is accomplished by injecting the provided liquid into the vial containing the lyophilized Herceptin.

23. The process of adding the provided liquid to the vial containing Herceptin powder is known as reconstruction. By reconstituting Herceptin based on the instructions provided by Genentech, a multi-dose solution is obtained.

24. Herceptin Prescription Information (attached hereto as **Exhibit 1**) instructs the healthcare providers to: “Reconstitute each 440 mg vial of Herceptin with 20 mL [milliliters]⁴ of Bacteriostatic Water for Injection (BWFI), USP, containing 1.1% benzyl alcohol as a preservative to yield a multi-dose solution containing 21 mg/mL trastuzumab.” *Id.* at 4.

¹ See <http://time.com/3541484/cancer-drug-price-hikes/> (last visited on May 6, 2016).

² One ounce contains 28349 mg.

³ The process of lyophilization (freeze-drying) allows a substance to be isolated from a solution under vacuum while being kept at low temperatures. This process is used to extract substances which would decompose upon heating.

⁴ One fluid ounce contains roughly 30 mL.

25. Depending on the purpose of the treatment, patients are to be given a dose of 2 to 8 mg Herceptin/Kg weight. For a person weighing about 150 lbs., that translates to an amount of Herceptin ranging from 136 mg to 544 mg.

26. Under the Heading of “*Dilution*,” Genentech instructs the providers to:

Determine the dose (mg) of Herceptin [see Dosage and Administration (2.1)]. Calculate the volume of the 21 mg/mL reconstituted Herceptin solution needed, withdraw this amount from the vial and add it to an infusion bag containing 250 mL of 0.9% Sodium Chloride Injection, USP.

Id.

27. When administering the required Herceptin dose to each patient, Plaintiff, as well as other Class Members, has prepared and administered Herceptin as instructed by Genentech, and in doing so relied upon Genentech’s express representation that the concentration of the reconstituted solution is 21 mg/mL.

28. In administering the Herceptin from the multi-dose vials, Plaintiff, as well as other Class Members, withdraws the amount of reconstituted Herceptin necessary for each patient until each vial is emptied.

29. Relying on Genentech’s representation that the reconstituted Herceptin solution has a concentration of 21mg/mL, Plaintiff and other Class Members provide sufficient volume of the solution to administer the required amount of Herceptin.

30. For instance, to treat a patient weighing 150 lbs. with a 2 mg/Kg dose of Herceptin for a weekly treatment, 6.5 mL of the reconstituted Herceptin solution would be required.⁵

31. Per the Prescription Information instructions, after reconstitution, the Herceptin solution should be used within 28 days and any unused Herceptin must be discarded after 28 days. For those patients who are allergic to benzyl alcohol, Herceptin is to be reconstituted with sterile water, and such solution is to be discarded immediately after use. *Id.*

⁵ 150 lbs. = 68 Kg x 2 mg Herceptin/Kg=136 mg Herceptin÷21 mg Herceptin/mL= 6.5 mL

C. Misrepresentations by Genentech

32. Herceptin vials are labeled as containing 45 mg of the drug. Genentech Prescription Information represents that its reconstituted multi-dose Herceptin solution contains 21 mg of Herceptin per each milliliter of the solution (21 mg/mL).

33. If each vial of Herceptin contains 440 mg as represented, for the reconstituted solution to have a concentration of 21 mg/mL, the volume of the resulting solution must be 20.95 mL [Concentration=weight (mg)/volume (mL)]. However, once the 20 mL of the diluent is injected into the vial containing Herceptin, the reconstituted solution has a volume of only about 20.2 mL.

34. This discrepancy would result from two possible scenarios:

(1) The Herceptin vial contains less Herceptin than stated. For a 20.2 mL solution of Herceptin to have a concentration of 21 mg/mL, the total amount of Herceptin present in the vial has to be 424.2 mg. Thus under this scenario (“*Scenario 1*”), the Herceptin vial contains about 16 mg less than that represented and warranted by Genentech; *or*

(2) The vial contains 440 mg Herceptin as stated, but the concentration of the solution is not 21 mg/mL as Genentech represents. A 21.2 mL solution containing 440 mg of Herceptin would have a concentration of 21.8 mg/mL, and not the 21 mg/mL represented and warranted by Genentech (“*Scenario 2*”).

35. Under either of the above Scenarios, Genentech is clearly misrepresenting the amount of Herceptin available for use by Plaintiff and other Class Members.

36. Under *Scenario 1*, Genentech is selling an amount of Herceptin that is less than what it has represented and warranted.

37. Under *Scenario 2*, Genentech is providing the represented amount of Herceptin in each vial, but misrepresents the concentration of the reconstituted Herceptin solution. As a result of such misrepresentation, Plaintiff and other Class Members unwittingly use *more Herceptin than intended and required*. As a result, the patient receives an overdose of Herceptin, and Plaintiff and other Class Members are forced to buy more Herceptin than actually needed.

38. Under either scenario, Genentech's misrepresentations caused Plaintiff and other Class Members to purchase additional Herceptin vials.

39. The damages suffered by Plaintiff and other Class Members are enhanced by the fact that once reconstituted, the Herceptin solution has a limited shelf life and has to be discarded after 28 days if reconstituted in BWFI, and immediately if reconstituted in water. This factor has an even greater impact for smaller hospitals or cancer clinics which do not treat a large number of qualified cancer patients.

CLASS ACTION ALLEGATIONS

40. Plaintiff seeks relief in its individual capacity and seeks to represent a class consisting of all others similarly situated. Pursuant to Fed. R. Civ. P. 23(a) and (b)(2) and/or (b)(3), Plaintiff seeks certification of a Class initially defined as follows:

All purchasers of Genentech-manufactured Herceptin from 1998 to the present.

41. Excluded from the Class are Defendants and their subsidiaries and affiliates, Defendants' executives, board members, legal counsel, and their immediate families.

42. Plaintiff reserves the right to amend or modify the Class definition with greater specificity or further division into subclasses or limitation to particular issues.

43. **Numerosity.** Fed. R. Civ. P. 23(a)(1). The potential members of the Class as defined are so numerous that joinder of all members is unfeasible and not practicable. While the precise number of Class Members has not been determined at this time, Plaintiff is informed and believes that Defendants, during the relevant time period, wrongfully marketed the Product to all hospitals and clinics involved in treating cancer patients. Defendants' records will provide information as to the number, location, and identification of all Class Members.

44. **Commonality.** Fed. R. Civ. P. 23(a)(2) and (b)(3). There are questions of law and fact common to the Class, which predominate over any questions affecting only individual Class Members. These common questions of law and fact include, without limitation:

- a. Whether Defendants misrepresented the amount of Herceptin present in each sold vial of the drug;

- b. Whether Defendants misrepresented the concentration of the reconstituted Herceptin;
- c. Whether Defendants' representations and promotional programs were untrue and/or misleading;
- d. Whether Defendants' misrepresentations regarding the Product resulted in overcharges to Plaintiff and Class Members;
- e. Whether Defendant violated California Business and Professions Code sections 17500, *et seq.*; and
- f. Whether Defendant violated California Business and Professions Code sections 17200, *et seq.*

45. **Typicality.** Fed. R. Civ. P. 23(a)(3). The claims of the named Plaintiff are typical to the claims of the Class. Plaintiff and all Class Members were exposed to uniform practices and sustained damages arising out of and caused by Defendants' unlawful conduct.

46. **Adequacy of Representation.** Fed. R. Civ. P. 23(a)(4). Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Counsel representing Plaintiff is competent and experienced in litigating class actions.

47. **Superiority of Class Action.** Fed. R. Civ. P. 23(b)(3). A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all the members of the Class is impracticable. Furthermore, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and potentially conflicting adjudication of the claims asserted herein. While certain individual claims concerning the controversy at issue have already been initiated by a few Class Members, a class action would indeed provide a superior vehicle for resolving the issue for all similarly affected and situated, because based upon the considerable anticipated expense of discovery and case preparation, completion of individual cases is not financially feasible for most Class Members especially considering the amount of damages in play for each member of the Class. This forum is appropriate because Defendants are headquartered in this District and the conduct at issue

emanated from this District. There will be no difficulty in the management of this action as a class action.

48. **Injunctive and Declaratory Relief. Fed. R. Civ. P. 23(b)(2).** Defendants' actions regarding the marketing, promotion, packaging and pricing of the Product are uniform to members of the Class. Defendants have acted or refused to act on grounds that apply generally to the Class, so that final injunctive relief or declaratory relief as requested herein is appropriate respecting the Class as a whole.

49. **Notice to the Class.** Plaintiff contemplates that the eventual issuance of notice to the proposed Class Members would set forth the subject and nature of the instant action. Plaintiff believes that Defendants' records, or records of Herceptin distributors, as to the names and addresses of individual purchasers of the products at issue are sufficient for direct mail notice to reach the vast majority of putative Class Members. To the extent that any further notices may be required, published notice in appropriate professional publications and journals can also be provided.

FIRST CAUSE OF ACTION

Breach of Express Warranty

50. Plaintiff, on behalf of itself and all others similarly situated, repeats and re-alleges the foregoing paragraphs, inclusive, and incorporates the same as if set forth herein at length.

51. Genentech has marketed Herceptin through general and specialty distributors.

52. Genentech has made express warranties regarding the quantity of Herceptin in each sold vial (440 mg), and the concentration of reconstituted Herceptin (21 mg/mL).

53. Defendants knew or should have known that their representations and warranties that a vial of the Herceptin contains 440 mg of this drug, or their representation that each mL of the reconstituted Herceptin solution contains 21 mg of this drug, were untrue or misleading. Defendants made these representations and warranties with the intent to induce Plaintiff and Class Members into purchasing more Herceptin than they required.

54. Plaintiff relied on Defendants' representations and warranties regarding the quantity of Herceptin in each sold vial and the concentration of reconstituted Herceptin

1 purchased from Genentech. These representations and warranties were material in influencing
2 Plaintiff's decision regarding the quantities of the Product needed and purchased.

3 55. As a result of Genentech's breach of express warranty, Plaintiff has suffered
4 damages in fact, lost money and property, and continues to be damaged, due to the additional
5 vials of Herceptin it was and is forced to purchase.

6 **SECOND CAUSE OF ACTION**

7 ***Breach of Implied Warranty of Merchantability***

8 56. Plaintiff, on behalf of itself and all others similarly situated, repeats and re-alleges
9 the foregoing paragraphs, inclusive, and incorporates the same as if set forth herein at length.

10 57. Genentech has marketed Herceptin through general and specialty distributors.

11 58. In marketing Herceptin as a merchantable product, Genentech was required to
12 provide goods that would conform to the promise or affirmations of fact made on the container
13 or label of the Product.

14 59. Genentech breached its warranty of merchantability by providing Plaintiff and
15 others similarly situated with Herceptin that did not conform to the promise and affirmation of
16 the quantity represented and warranted by Genentech.

17 60. Plaintiff relied on Defendants' representations and affirmations regarding the
18 quantity of Herceptin in each sold vial and the concentration of reconstituted Herceptin purchased
19 from Genentech. These representations and affirmations were material in influencing Plaintiff's
20 decision regarding the quantities of the Product needed and purchased.

21 61. As a result of Genentech's breach of the implied warranty of merchantability,
22 Plaintiff has suffered damages in fact, lost money and property, and continues to be damaged,
23 due to the additional vials of Herceptin it was and is forced to purchase.

24 **THIRD CAUSE OF ACTION**

25 ***Violation of the False Advertising Law***

26 ***(Cal. Bus. & Prof. Code § 17500)***

27 62. Plaintiff, on behalf of itself and all others similarly situated, repeats and re-alleges
28 the foregoing paragraphs, inclusive, and incorporates the same as if set forth herein at length.

63. Defendants have engaged in false advertising within the meaning of California Business and Professions Code sections 17500, *et seq.* based on the conduct herein alleged. As a result of Defendants' conduct, Plaintiff suffered injury in fact and lost money or property.

64. Defendants' representations and actions emanate from their headquarters, which are based in this state, and were disseminated to the public in California and other states.

65. Defendants represented that one vial of the Product contains 440 mg Herceptin and that the reconstituted solution of Herceptin has a concentration of 21 mg/mL.

66. Defendants knew or should have known that their representations that a vial of the Product contains 440 mg Herceptin, and that the reconstituted solution of Herceptin has a concentration of 21 mg/mL, were untrue or misleading. Defendant made these representations with the intent to induce Plaintiff and Class Members into purchasing more Product than they needed.

67. Plaintiff relied on Defendants' representations and non-disclosures. These representations and non-disclosures played a significant part in influencing Plaintiff's decision to purchase more Herceptin than necessary. Plaintiff suffered injury in fact and lost money and property as a result of the misconduct alleged herein.

68. Pursuant to California Business and Professions Code Section 17535, Plaintiff and Class Members seek all relief available thereunder, including equitable relief, in the form of restitution or disgorgement, by Defendants for unneeded Herceptin that Plaintiff and Class Members were forced to buy because of Defendants' unlawful and unfair business practices, and/or disgorgement of all revenues, earnings, profits, Defendants' compensation and benefits which may have been obtained by Defendants as a result of such business acts or practices; and an injunction enjoining Defendants from their unlawful and unfair business activities as alleged herein.

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FOURTH CAUSE OF ACTION

Violation of the Unfair Competition Law

(Cal. Bus. & Prof. Code §§ 17200 et seq.)

69. Plaintiff, on behalf of itself and all others similarly situated, repeats and re-alleges the foregoing paragraphs, inclusive, and incorporates the same as if set forth herein at length.

70. Defendants have engaged in unlawful, unfair, and fraudulent business acts within the meaning of California Business and Professions Code sections 17200, *et seq.* based on the conduct herein alleged. As a result of Defendants' conduct, Plaintiff suffered injury in fact and lost money or property.

71. Defendants' unlawful business practices include, but are not limited to:

- a. Misrepresenting the amount of Herceptin in each vial sold;
- b. Misrepresenting the concentration of the reconstituted Herceptin.

72. Defendants' business practices are unlawful in that their conduct constitutes a violation of the False Advertising Law (Cal. Bus. & Prof. Code, §§ 17500 *et seq.*).

73. Defendants' unfair business practices include, but are not limited to:

- a. Misrepresenting the amount of Herceptin in each vial sold;
- b. Misrepresenting the concentration of the reconstituted Herceptin.

74. Defendants' business practices are unfair because they forced Plaintiff and others similarly situated to purchase more Herceptin than necessary. Defendants' practices are unethical, oppressive, unscrupulous and/or substantially injurious to Plaintiff and Class Members. Defendants draw significant economic benefits from the sale of Herceptin and further economic benefit to Defendants cannot justify the economic loss and injury suffered by Plaintiff and Class Members.

75. Defendants' unfair business practice caused Plaintiff substantial harm in the amount of thousands of dollars spent on purchasing unnecessary Herceptin. Defendants' unfair practice is not outweighed by any countervailing benefit to Plaintiff or Class Members. Plaintiff could not have reasonably avoided this harm while simultaneously complying with the Product's express usage guidelines

1 76. Defendants' fraudulent business practices include, but are not limited to:

2 a. Misrepresenting the amount of Herceptin in each vial sold;

3 b. Misrepresenting the concentration of the reconstituted Herceptin.

4 77. Defendants' business acts are fraudulent because Defendants' representations
5 were likely to deceive reasonable people and did deceive Plaintiff and Class Members into
6 purchasing more Herceptin than necessary.

7 78. Defendants made the representations, *supra*, while knowing that they either
8 provided less Herceptin than represented or that they misrepresented the concentration of the
9 reconstituted solution of Herceptin.

10 79. In reliance on Defendants' representations, Plaintiff was forced to purchase more
11 Herceptin than necessary and suffered actual and monetary injury.

12 80. Plaintiff has standing to pursue this claim because it has suffered injury in fact
13 and loss of money and/or property as a result of the wrongful conduct alleged herein.
14 Defendants' business acts and practices, as alleged herein, have caused injury to Plaintiff and the
15 Class.

16 81. Pursuant to California Business and Professions Code Section 17203, Plaintiff
17 and Class Members seek all relief available thereunder including, equitable relief, in the form of
18 restitution or disgorgement, by Defendants for the unnecessary Herceptin that Plaintiff and Class
19 Members were forced to purchase because of Defendants' unlawful and unfair business
20 practices, and/or disgorgement of all revenues, earnings, profits, Defendants' compensation and
21 benefits which may have been obtained by Defendants as a result of such business acts or
22 practices, and an injunction enjoining Defendants from their unlawful and unfair business
23 activities as alleged herein.

24 **FIFTH CAUSE OF ACTION**

25 ***Unjust Enrichment***

26 82. Plaintiff, on behalf of itself and all others similarly situated, repeats and re-alleges
27 the foregoing paragraphs, inclusive, and incorporates the same as if set forth herein at length.
28

1 7. An award for attorneys' fees; and

2 8. For such other and further relief as the Court deems just and proper.

3 **DEMAND FOR A JURY TRIAL**

4 Plaintiff demands a jury trial for the Class on all claims so triable to a jury.

5 Respectfully Submitted,

6 By: /s/ Elise Sanguinetti

7 DATED: May 9, 2016

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